HFD-613

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 29 1998

NDA 17-820/S-036

Lilly Research Laboratories
Attention: Gregory T. Brophy, Ph.D
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Brophy:

Please refer to your April 21, 1998 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutrex (dobutamine HCl) Injection 12.5 mg/ml.

We acknowledge receipt of your submission dated July 23, 1998

This supplemental new drug application provides for draft labeling revised to add information relating to the dosing of these products in the pediatric population as required in the December 13, 1994 Federal Register notice entitled: "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of 'Pediatric Use' subsection in the Labeling" and, as amended, to update the INDICATIONS AND USAGE section by providing the most recent dosing recommendations for the use of intravenous inotropic compounds.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling included in your July 23, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling included in your July 23, 1998 submission. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days afler it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-820/S-036." Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

RL 7/29/98

Raymond J. Lipicky, M.D.
Director
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